

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 42 and 50-53 currently are pending, and are directed to a method for the detection of *L. brevis* in a sample.

The Amendments to the Claims

Claim 42 has been amended to include specific hybridization conditions and to delete reference to nucleic acid sequences that are 70% identical to SEQ ID NOs: 1, 21, 73 or 74. This amendment to claim 42 is supported by the published specification at, for example, pages 9 and 10, bridging paragraph. Claim 42 also has been amended to incorporate the subject matter of claims 55 and 56, and to correct formal matters. Claims 54, 55, 56, and 64 have been cancelled. Accordingly, no new matter has been added by way of these amendments.

The Office Action

The Office Action raises the following concerns:

- (a) claims 42, 50-56, and 64 are rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description,
- (b) claims 42, 50, 53, 54, 55, and 64 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent 5,484,909 (Nietupski et al.) (“the Nietupski patent”),
- (c) claims 42, 50, 53, 54, 55, and 64 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Japanese Patent Application No. 6-141899 (“the Japanese application”),
- (d) claim 51 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Nietupski patent in view of U.S. Patent 5,792,607 (Backman et al.) (“the Backman patent”),

(e) claim 52 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Nietupski patent in view of U.S. Patent 5,744,311 (Frasier et al.) (“the Frasier patent”), and

(f) claim 56 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Nietupski patent in view of U.S. Patent 5,738,993 (Fugono et al.) (“the Fugono patent”).

Reconsideration of these rejections is respectfully requested.

Discussion of Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 42, 50-56, and 64 have been rejected under Section 112, first paragraph, for allegedly not complying with the written description requirement. This rejection is traversed for the reasons set forth below.

The Office Action maintains that the specification does not adequately describe the broad scope of the probe and primer nucleic acid molecules recited in the rejected claims. The Office Action further contends that only SEQ ID NOs: 1, 21, 73, and 74 are adequately described in the specification. Applicants respectfully disagree. From the disclosure of SEQ ID NOs: 1, 21, 73, and 74, one of ordinary skill in the art would have recognized that the present application also contemplates fragments of SEQ ID NOs 1, 21, 73, and 74 comprising at least 15-30 nucleotides, as well as homologs of SEQ ID NOs 1, particular using the hybridization conditions set forth in claim 42, as amended. With regard to nucleic acid complements of SEQ ID NO: 1, 21, 73, or 74, one of ordinary skill in the art would recognize that an DNA or RNA molecule complementary to SEQ ID NO: 1, 21, 73, or 74 is contemplated by the subject application, and could be easily identified by an ordinarily skilled artisan using routine methods known in the art.

In view of the foregoing, the written description requirement is satisfied with respect to claim 42, as well as claims 50-53 depending therefrom. Thus, the Section 112, first paragraph, rejection of the claims as lacking adequate written description should be withdrawn.

Discussion of Rejections Under 35 U.S.C. § 102

Claims 42, 50, 53, 54, 55, and 64 have been rejected under Section 102(b) as allegedly anticipated by the Nietupski patent and the Japanese application. Claim 42, as amended, is directed to a method of detecting *L. brevis* in a sample comprising the use of primers of SEQ ID NO: 1, 21, 73, or 74, fragments thereof, or sequences which hybridize thereto in combination with probes of SEQ ID NO: 21, 73, or 74, fragments thereof, or sequences which hybridize thereto. SEQ ID NOs: 21, 73, and 74 are derived from nucleotides 100-173 of SEQ ID NO: 1 and are species-specific for *L. brevis*.

In contrast, the Nietupski patent discloses a method for detecting beer spoilage microorganisms in a sample using sequences corresponding to nucleotides 192-201 and 202-209 of SEQ ID NO: 1 as probes and primers. The sequences disclosed in the Nietupski patent are derived from the 16S or 23S rRNA of *L. brevis* (see col. 5, line 24 and col. 6, lines 45-66), which rRNAs are sequences of several thousand nucleotides. These sequences are the target sites for obtaining specific probes (see col. 5, lines 23-26). The Japanese application discloses a method for detecting *Lactobacilli*, but not specifically *L. brevis*, in a sample using a nucleic acid sequence corresponding to nucleotides 176-195 of SEQ ID NO: 1, which is not specific for *L. brevis*, but only for the higher taxonomic unit of *Lactobacilli* (see abstract).

The sequences disclosed in the Nietupski patent and the Japanese application do not overlap with SEQ ID NO: 21, 73, or 74. Moreover, neither the Nietupski patent nor the Japanese application discloses amplification and detection of *L. brevis* nucleic acid sequences in a sample using the combination of species-specific probes and primers, both derived from the intergenic 23S-5S rDNA spacer of *L. brevis*, as recited in claim 42. The 23S-5S rDNA spacer region is a novel non-coding region of the *L. brevis* genome of a few hundred nucleotides in length. Surprisingly, in this short region species-specific sequences were identified which are suitable as species-specific probes and primers for the detection of *L. brevis* (see present specification at page 8, second paragraph).

Accordingly, neither the Nietupski patent nor the Japanese application discloses the subject matter of claim 42, or claims 50-53 depending therefrom. Thus, the anticipation rejections of the pending claims under Section 102(b) should be withdrawn.

Discussion of Rejections Under 35 U.S.C. § 103

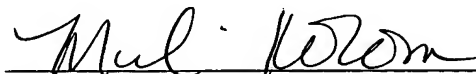
Claims 51, 52, and 56 are rejected under Section 103(a) as allegedly unpatentable over the Nietupski patent in view of the Backman patent, the Frasier patent, and the Fugono patent, respectively. Claim 56 has been cancelled, thereby mooted the rejection of this claim. As discussed above, the Nietupski patent does not disclose the subject matter of claim 42, and, therefore, also does not disclose the subject matter of dependent claims 51 and 52. The Backman, Frasier, and Fugono patents are relied upon as allegedly compensating for the deficiencies of the Nietupski patent with respect to the subject matter of claims 51 and 52. The Backman, Frasier, and Fugono patents, however, do not disclose or suggest a method of detecting *L. brevis* in a sample comprising the use of SEQ ID NO: 1, 21, 73 or 74, fragments thereof, or sequences which hybridize thereto.

In view of the forgoing, the subject matter of claims 51 and 52 is not obvious over the cited references, alone or in combination. As such, the Section 103(a) rejections should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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Date: November 30, 2005